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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,181	11/10/2000	Steven D. Jensen	7678.350.2	4245

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Workman Nydegger
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/710,181	JENSEN ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *,42,44-48,50-54,56-63,65-68,70-87,91-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *,42,44-48,50-54,56-63,65-68,70-87,91-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/18/10 have been fully considered but they are not persuasive. See argument below. Previous rejections and other issues not addressed below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases, “the carrier being free of an amount of an abrasive that would externally abrade a tooth surface” and “does not externally abrade a tooth surface when applied thereto” appear to be new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin (USPN 6108850;8/29/00) and Shimada et al (USPN 5626837; 5/6/97). McLaughlin teaches a composition for whitening teeth comprising a bleaching agent such as 10% hydrogen peroxide and an agent for reducing tooth sensitivity such as 1% potassium nitrate. See column 4 lines 5-12, column 7 Example 4. McLaughlin suggests bleaching agents other than hydrogen peroxide (e.g. 10 to 40% carbamide peroxide or carbamyl peroxide) can be used in the composition. See column 2 line 15 – column 3 line 7. McLaughlin suggests that the composition can further comprise water , polyethylene glycol (see column 2 line 64 – column 3 line 7), xantham gum (column 3 lines 38—61) and stannous fluoride (column 3 line 62 - column 4 line 4). McLaughlin teaches a method of applying the composition to teeth for the purpose of whitening teeth. McLaughlin teaches that the composition can be applied using a dental tray. See column 4 line 59 - column 5 line 15. McLaughlin teaches all that is recited in claims 52,54 and 74-76 except for the invention comprising an antimicrobial agent such as cetyl pyridinium bromide and stabilizer such as citric acid as well as the length of time the teeth are subjected to dental tray application. However, Shimada et al teach dental compositions (toothpaste, mouthwash, etc.) comprising antimicrobial agents such as cetyl pyridinium chloride, pH adjustors such as citric acid, actives such as stannous fluoride and humectants such as polyethylene glycol (see abstract, column 1 lines 17- 42, column 3 line 57 – column 4 line 31). It would have been obvious to one having ordinary skill in the art to modify the invention of McLaughlin to include the cetyl pyridinium halide and the citric acid taught by Shimada

et al. One would have been motivated to do this since both inventions are to dental / oral compositions for the protection and healthy maintenance of teeth. In addition one would have been motivated to do this in order to protect the teeth and gums from bacterial infection, and one would have been motivated to employ citric acid in order to adjust the pH of the composition to a stable environment. With respect to the time length of applying the dental tray to the teeth, one having ordinary skill in the art would have been motivated to determine the optimum time range in order to obtain the best result of whitening and protecting teeth.

Response to Applicants' Argument

Applicants have amended the claims to recite, "the carrier being free of an amount of an abrasive that would externally abrade a tooth surface". McLaughlin teaches that water and thickner are optional components of the vehicle and are included whenever an abrasive material is included in the vehicle. The paste carrier of Example 4 of McLaughlin also includes an abrasive (column 3 lines 50-61 and column 7 lines 1-26). The Applicants further argue that Example 4 of McLaughlin includes both a solvent and paste carrier while being substantially free of abrasives. Neither McLaughlin nor Shimada et al. teach or suggest a composition that is substantially free of abrasives. The Examiner argues that the claim language, "the carrier being free of an amount of an abrasive that would externally abrade a tooth surface" does not exclude an abrasive. Therefore, claims as written allow for the inclusion of an abrasive. The Examiner further argues that there exists no need for McLaughlin or Shimada et al. to teach a composition that is substantially free of abrasives since the instant claim language does

not exclude abrasive. Applicants argue that the instant claims are patentable over McLaughlin and Shimada et al. because they contact teeth without scrubbing or brushing. In contrast, McLaughlin discloses application of toothpaste to teeth using a toothbrush. The Examiner argues that McLaughlin discloses methods of applying the dental composition in the form a mouthwash, bleaching composition and by way of a dental tray (column 4 line 26 – column 6 line 59). These application methods differ from the toothbrush application method. The Examiner argues that McLaughlin does not have to spell out all scenarios to make an application method obvious. McLaughlin generally teaches other methods beside toothpaste application method. Applicants provide citations in Exhibits A,B,C,D and E to support that toothpaste contain abrasives. The Examiner reiterates the claims as written do not exclude abrasives. Claims 41 and 72 uses 10% to about 30% peroxide and about 0.01% to about 2% of potassium nitrate, claims 59 and 77 uses 10% to about 20% peroxide and about 0.05% to about 1% of potassium nitrate, claims 65 and 81 uses 10% to about 30% peroxide and about 0.05% of potassium nitrate and claim 86 uses 10% to about 20% peroxide and about 0.01% to about 2% of potassium nitrate. Applicants argue that the results at pages 15-16 of the reply filed 6/2/0/09 (which the same results presented on pages 26-28 of the instant specification) support claim ranges of peroxide and potassium nitrate. The Examiner reiterates that McLaughlin in Example 4 disclose a composition comprising 10% hydrogen peroxide and 1% potassium nitrate. The Examiner maintains that Example 4 of McLaughlin reads on the instant independent claims with respect to % amounts of peroxide and potassium nitrate. The Examiner maintains that the Applicants only

provide unexpected results for a composition comprising 0.5% potassium nitrate and 10.5% carbamide peroxide (see pages 26-28 of instant specification or pages15-16 of Applicants' reply filed 6/2/09). The Examiner reiterates that the Applicants have not provided unexpected data for the % ranges of potassium nitrate or for the % ranges and types of peroxides claimed. Since the prior art disclose an invention comprising 1% potassium nitrate and 10% hydrogen peroxide, it would have been obvious to develop the instant invention in light of McLaughlin (i.e. it would have been obvious to make an invention comprising the instant % amount ranges of potassium nitrate and peroxide). For this reason, the Applicants' argument regarding the trends of claimed % ranges for potassium nitrate and peroxide is not convincing, and therefore, it is imperative that Applicants claim unexpected results or provide ample unexpected results to cover the scope of % ranges recited in the claims. Thus, the unexpected result provided on pages 26-28 is not commensurate in scope with the instant claims.

The Applicants argue that instant claims are to an invention substantially free of abrasives, i.e. the amount of abrasive in the invention is less than 20%. Applicants argue that McLaughlin's composition must contain more than 20% abrasive in the paste carrier. The Examiner argues that McLaughlin does not disclose an abrasive in his composition of Example 4. McLaughlin does not teach or suggest that the paste carrier therein for the composition comprise an abrasive. Therefore, McLaughlin meets the instantly claimed limitation of the present invention comprising substantially no abrasive (less than 20% abrasive). The Examiner awaits evidence from the Applicants supporting

that McLaughlin's composition in Example 4 contains an abrasive and the amount thereof if present).

The Applicants amended claims to recite the composition comprising about 3% to about 30% bleaching agent which is narrower than the original range of about 0.5 to about 50% bleaching agent. The Applicants argue that tested compositions comprising 10.5 and 15% bleaching agent show unexpected results that would represent the amended range of about 3 to about 30% bleaching agent. The Applicants argue that the further amended range in the claims of about 10 to about 20% is even better tailored than the tested compositions comprising 10.5 and 15 % bleaching agent.

The Examiner argues that the bleaching agent appears to be the key element for the invention. The Examiner maintains that the Applicants' results provided for compositions comprising 10.5 and 15 % bleaching agents would not represent the broad range of about 3% to about 30% bleaching agent since McLaughlin teaches a composition comprising 10% bleaching agent and 1% potassium nitrate. This teaching of McLaughlin also reads on the claimed composition comprising 10 to 20 % bleaching agent.

The Applicants argue that McLaughlin's Example 4 discloses a toothpaste comprising hydrogen peroxide and potassium, but no identifiable solvent or tackifying agent. The Applicants further argues that the combination of McLaughlin and Shimada et al. does not, without hindsight, suggest the combination of elements recited in claim 41 as amended.

The Examiner argues that McLaughlin only exemplifies a toothpaste. However, McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray that can be applied to teeth (column 4 line 59 – column 5 line 15). McLaughlin also teaches that the disclosed and suggested composition therein may comprise solvents and tackifying agent (column 3 lines 38-61).

The term toothpaste denotes an abrasive composition used to clean teeth when brushing. McLaughlin does not teach or suggest a dental formulation comprising a dental bleaching agent in the claimed amount and a carrier that contains a solvent and a tackifying agent to yield a bleaching composition free of abrasives.

The method steps in claims 72-85 are not suggested or taught by McLaughlin. The step of contacting a person's teeth with the dental bleaching composition (without scrubbing or brushing) for a sufficient time to bleach teeth is not taught by McLaughlin. The Examiner argues that McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray to be applied to teeth (column 4 line 59 – column 5 line 15). Such an application would not involve brushing or scrubbing the teeth.

Applicant argues that the only Example in McLaughlin includes a bleaching agent and potassium nitrate and the potassium nitrate is in an amount of 1%. As shown by Applicant in a comparative study, dental bleaching compositions that include 0.5% potassium nitrate provide the best reduction in sensitivity. The Examiner reiterates that the instant claims are broader in scope than the examples showing unexpected results

provided by the Applicants. Applicants provide unexpected results for an invention comprising 0.5% potassium nitrate and 10.5% or 15% carbamide peroxide. Applicants argue that McLaughlin's toothpaste composition in Example 4 contains abrasive, because the paste carrier recited as a component of the Example 4 composition contains the abrasive. Applicants argue that the abrasive material in McLaughlin's Example 4 is sufficient in quantity to impart an abrasive action meaning that the abrasive is present in more than 20%. Applicants provide website citations in Exhibits A, B and C to support that toothpaste contain abrasive. Applicants also provide Exhibits D and E to support that McLaughlin's toothpaste contain abrasive. The Examiner argues that the instant claims recite a composition that contains less than 20% abrasive (substantially abrasive free). Therefore, instant composition is not free of abrasive. The Examiner argues that Applicants merely state that toothpaste contains more than 20% abrasive. None of the websites in the Exhibit explicitly or implicitly define toothpaste as containing more than 20% abrasive. For this argument to be convincing the Applicants must provide evidence that toothpaste contain more abrasive than the composition claimed. At this time, Applicant has provided no evidence to convince the Examiner that McLaughlin does not read on instant claims, because McLaughlin's composition in Example 4 contains more than 20% abrasive.

The Applicant argues that claims 46, 65 and 81recite an amount of potassium nitrate (about 0.5%) in combination with other elements not taught or made obvious by McLaughlin. Also, claims 59 and 77 recite an amount of potassium nitrate (about 0.05-1%) in combination with other elements not taught or made obvious by McLaughlin.The

Examiner reiterates that McLaughlin in Example 4 disclose a composition comprising 10% hydrogen peroxide and 1% potassium nitrate. The Examiner maintains that Example 4 of McLaughlin reads on the instant independent claims with respect to % amounts of peroxide and potassium nitrate. The Examiner maintains that the Applicants only provide unexpected results for a composition comprising 0.5% potassium nitrate and 10.5% carbamide peroxide (see pages 26-28 of instant specification or pages15-16 of Applicants' reply filed 6/2/09). The Examiner reiterates that the Applicants have not provided unexpected data for the % ranges of potassium nitrate or for the % ranges and types of peroxides claimed. Since the prior art disclose an invention comprising 1% potassium nitrate and 10% hydrogen peroxide, it would have been obvious to develop the instant invention in light of McLaughlin (i.e. it would have been obvious to make an invention comprising the instant % amount ranges of potassium nitrate and peroxide). For this reason, the Applicants' argument regarding the trends of claimed % ranges for potassium nitrate and peroxide is not convincing, and therefore, it is imperative that Applicants claim unexpected results or provide ample unexpected results to cover the scope of % ranges recited in the claims. Thus, the unexpected result provided on pages 26-28 is not commensurate in scope with the instant claims. The Examiner argues that the bleaching agent appears to be the key element for the invention. The Examiner maintains that the Applicants' results provided for compositions comprising 10.5 and 15 % bleaching agents would not represent the broad range of about 3% to about 30% bleaching agent since McLaughlin teaches a composition comprising 10% bleaching

agent and 1% potassium nitrate. This teaching of McLaughlin also reads on the claimed composition comprising 10 to 20 % bleaching agent.

The Examiner argues that McLaughlin only exemplifies a toothpaste. However, McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray that can be applied to teeth (column 4 line 59 - column 5 line 15). McLaughlin also teaches that the disclosed and suggested composition therein may comprise solvents and tackifying agent (column 3 lines 38-61).

The term toothpaste denotes an abrasive composition used to clean teeth when brushing. McLaughlin does not teach or suggest a dental formulation comprising a dental bleaching agent in the claimed amount and a carrier that contains a solvent and a tackifying agent to yield a bleaching composition free of abrasives.

The method steps in claims 72-85 are not suggested or taught by McLaughlin. The step of contacting a person's teeth with the dental bleaching composition (without scrubbing or brushing) for a sufficient time to bleach teeth is not taught by McLaughlin.

The Examiner argues that McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray to be applied to teeth (column 4 line 59 - column 5 line 15). Such an application would not involve brushing or scrubbing the teeth.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91- 93 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not identical, they are not patentably distinct from each other because Fischer (USPN

6306370) claims a composition comprising 3-20 % peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10 % potassium nitrate. The composition can further comprise carboxypolymethylene, polyols such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Fischer's invention (USPN 6306370) also claims a method to whitening (bleaching) teeth with the composition with the aid of a tray. Fischer's invention (USPN 6306370) discloses amounts of potassium nitrate (0.1-10 %) and peroxide (3-20 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6306370) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the invention (USPN 6306370) was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6306307 amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, the Examiner argues that the declaration is not commensurate in scope with claims because the claims recite a range of 3-30% peroxide and applicants' declaration only shows results for ranges of peroxide being 10% or 15%. In the previous rejection mailed 4/16/08, the Examiner inadvertently left claims 72-86 out of the 103(a) rejection. Note it is obvious that the Examiner intended to include claims 72-86 in the rejection

since the prior art cited suggests the combination of potassium nitrate, bleaching agent, solvent and tackifying agent as described in the office action mailed 4/16/08.

Response to Applicants Argument

Applicants argue that '370 do not make claim to a method of bleaching and desensitizing teeth by applying to teeth a bleaching and desensitizing composition without brushing or scrubbing. The Examiner argues that claim 15 of '370 makes claim to a method for whitening teeth by scrubbing or brushing. Applicants argue that instant claims recite 0.01% -2% potassium nitrate (species) whereas claims in '370 do not recite this narrow range of potassium nitrate. The Examiner argues that '370 makes claim to 0.1 to 10% potassium nitrate (genus) which overlaps with instantly claim range of potassium nitrate ('370 claim 16). Thus, the potassium nitrate range in '370 makes obvious the claimed potassium nitrate range obvious. Applicants argue that in light of the '370 specification an artisan would have predicted that a small quantity of potassium nitrate within the claimed range would have yielded less oral sensitivity than a larger quantity of potassium nitrate. The Examiner reiterates that the Applicants only provide unexpected results for a composition comprising 0.5% potassium nitrate and 10.5% carbamide peroxide (see pages 26-28 of instant specification or pages15-16 of Applicants' reply filed 6/2/09). The Examiner reiterates that the Applicants have not provided unexpected data for the % ranges of potassium nitrate or for the % ranges and types of peroxides claimed.

Applicants argue that instant claims 41 and 72 uses 10% to about 30% peroxide and about 0.01% to about 2% of potassium nitrate, claims 59 and 77 uses 10% to about

20% peroxide and about 0.05% to about 1% of potassium nitrate, claims 65 and 81 uses 10% to about 30% peroxide and about 0.05% of potassium nitrate and claim 86 uses 10% to about 20% peroxide and about 0.01% to about 2% of potassium nitrate. Applicants argue that the results in the specification on pages 26-28 provide results to support claimed ranges of peroxide and potassium nitrate. The Examiner reiterates USPN '370 make claim to a composition comprising 3 to 20 % bleaching agent (peroxide) and at least 0.1% as well as from about 0.1% to about 10% potassium nitrate. USPN '370 claims read on the instant independent claims with respect to the amounts of bleaching agent (peroxide) and potassium nitrate. The Examiner reiterates that the Applicants only provide unexpected results for a composition comprising 0.5% potassium nitrate and 10.5% carbamide peroxide (see pages 26-28 of instant specification or pages15-16 of Applicants' reply filed 6/2/09). The Examiner reiterates that the Applicants have not provided unexpected data for the % ranges of potassium nitrate or for the % ranges and types of peroxides claimed. Since USPN '370 make claim to an invention comprising 3 to 20 % bleaching agent (peroxide) and at least 0.1% as well as from about 0.1% to about 10% potassium nitrate, it would have been obvious to make claim to an invention comprising the instant ranges of potassium nitrate and peroxide. For this reason, the Applicants' argument regarding the trends of claimed % ranges for potassium nitrate and peroxide is not convincing, and therefore, it is imperative that Applicants claim unexpected results or provide ample unexpected results to cover the scope of % ranges recited in the claims. Thus, the unexpected result is not commensurate in scope with the instant claims.

Applicants make several arguments as to why the rejection should be withdrawn. Applicants provide declarations to support their position. Applicants also point out that a double patenting rejection is over the claims not the body of the disclosure. Applicants argue that Fischer declaration explains that low concentration of potassium nitrate rather than larger quantities of potassium nitrate surprisingly reduced tooth and oral sensitivity caused by bleaching agent. Applicants argue that USPN '370 actually suggest potassium nitrate in a broad range of 0.1 to 50%. The broad potassium nitrate range suggested by '370 is hardly suggestive of the narrow range of 0.01-2% set forth in the instant claims. Specifically claim 1 claims at least 0.1 potassium nitrate, claim 2 claims 1-7% potassium nitrate and claims 14 and 16caims 0.1 to about 10% potassium nitrate. It is clear from the comparative study that changing the concentration of bleaching agent form 10 to 15% had virtually no effect on relative tooth and oral sensitivities, while changing the concentration of potassium nitrate from the accepted 3% to 0.5% overwhelming reducing tooth and oral sensitivities. The Examiner reiterates that Applicants have only provided a showing of unexpected results for 0.5% potassium nitrate combined with 10 or 15% bleaching agent. The Examiner argues that this one tested concentration of 0.5% potassium nitrate is not convincing of the claim range of 0.01-2% potassium nitrate and the 15% tested concentration of bleach agent is not convincing of 30% bleaching agent.. Thus, claims are not commensurate in scope with the unexpected results.

The Examiner agrees with the point made by the Applicants that a double patenting rejection is over the claims not the body of the disclosure. It is for that very reason the double rejection over USPN '370 is maintained.

A) Note that Applicants' claims are to a dental bleaching composition comprising:

1) 10 to about 30 % peroxide as to have a tooth bleaching effect;

2) about 0.05 to about 1 % potassium nitrate as to result in reduced tooth sensitivity that may be caused by the peroxide; and

3) a carrier.

B) Note that USPN '370 makes claim (see claim 14) to a dental bleaching composition comprising:

1) about 3 to about 20% peroxide;

2) about 0.01 to about 10% potassium nitrate in an amount to reduce tooth sensitivity that may be caused by the peroxide; and

3) a carrier.

In the comparison of Applicants' claims with USPN '370 claims, the claims in USPN '370 makes obvious instant claims. Note instant claims to composition comprising 10% to about 30 % peroxide overlaps USPN's peroxide range of about 3% to about 20% peroxide. Note that instant claims to composition comprising about 0.05 to about 1 % potassium nitrate fall within the range (about 0.01 to about 10%) claimed in USPN '370. Therefore, USPN '370 claims makes obvious the instant claims. Applicants provide unexpected for a composition comprising 10 or 15 % peroxide and 0.5 %

potassium nitrate (see evidence appendix). As recited in office action of 4/5/2005, the Examiner agrees that results are convincing as well as unexpected. However, the Examiner maintains that the claims are not commensurate in scope with the examples tested. For this reason, the rejection is maintained. Applicants argue that the criticality of the invention lies within the amount of potassium nitrate not in the amount of peroxide. This may be true, however, this statement is not convincing since Applicants only provide data for 10% and 15% peroxide in the broad range of about 3 to about 30% peroxide instantly claimed. For the above reasons USPN '370 is cited as an obviousness-type double patenting rejection over instant claims.

The data are not commensurate in scope with the Examples provided at pages 26-28 of the specification. The claimed ranges of 0.05 - 1 % potassium nitrate and 10 - 30% carbamide peroxide are not commensurate in scope with the unexpected results since the only data point tested involves a composition comprising 0.5% potassium nitrate and 10.5% carbamide peroxide.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/

Primary Examiner, Art Unit 1616